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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,391	02/07/2002	Barrie Mills	FHW-085US	3759

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LAHIVE & COCKFIELD, LLP.  
28 STATE STREET  
BOSTON, MA 02109

EXAMINER
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TRUONG, LINH T

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 04/22/2004

*8*

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/936,391

Applicant(s)

MILLS ET AL.

Examiner

Linh Truong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 42-77 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 42-49, 51-70, 73 and 74 is/are rejected.
- 7) ☒ Claim(s) 50, 71, 72 and 75-77 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 6
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_

## **DETAILED ACTION**

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the frusto-conical ring in claim 1 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

The drawings are objected to under 37 CFR 1.83(a) because they fail to show deformable pad 101 (as stated on page 7, line 30 in the specification). Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### ***Claim Objections***

Claims 42-77 are objected to because of the following informalities: "...wherein the opening is surrounded by one (i) a pliable unreinforced convex formation on a bodyside face of the pad; and (ii) a hollow frusto-conical ring extending outwardly from a bodyside face of the pad. " The specification does not show or explain how/why the

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convex formation and the hollow frustonical ring extending outwardly are both on the bodyside face of the pad as claimed in claim 42. It does not make sense since, when in use, the convex formation of the adhesive pad will abut the user's abdomen but the frusto-conical ring would not also fit onto the user's abdomen and vice versa. On page 2, lines 13-16 of the specification, it first states, "...in one aspect, the invention provides a deformable pad...surrounded by a pliable unreinforced convex formation on a bodyside face of the pad." And then, on page 2, lines 30-33, the specification states, "In another aspect, the invention provides a deformable pad ... the opening being surrounded by a hollow frusto-conical ring extending outwardly from the bodyside face of the pad." According to the the specification, there are two different embodiments of the deformable pad. For the purposes of examination, only one of the embodiments will be examined, not a deformable pad with both a convex formation and a frusto-conical ring on the same surface of the pad. Appropriate correction is required.

Claim 69 is objected to because of the following informalities: the phrase "for removably securing an ostomy bag to the skin of a patient" is out of context and should be deleted. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 42-49, 51-70, and 73-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Botten et al. (Botten) '6,106,507 in view of Neumeier '3,964,485.

For claim 42 and 48, Botten teaches an ostomy appliance with a deformable pad 11 having a plastics film 13 bonded to an adhesive material (col.2, lines 60-64 and col. 3, lines 33-35) and an aperture 15. Botten, however, does not teach that the aperture is surrounded by a pliable unreinforced convex formation on the bodyside face of the pad. Convex formations are well known in the ostomy art for making adhesive pads fit better to a user's abdomen. Neumeier teaches an ostomy appliance with pad 30 with a pliable unreinforced convex portion 32 on the bodyside face of the pad (fig. 3, col.2, lines 50-59). Therefore it is obvious to one with ordinary skill in the art at the time the invention was made to provide the adhesive pad of Botten with the convex formation of Neumeier for a better fitting ostomy appliance to provide comfort and prevent leakage of fluids.

For claims 43-46, Botten teaches that the adhesive pad comprise a hydrocolloid composition or a hydrogel adhesive, wherein the hydrocolloid composition comprises gel-forming natural and modified polysaccharides in combination with polymers based on styrene, isoprene, and isobutylene and wherein the hydrogel adhesive comprises an adhesive water swellable polymer and is formed of a polymeric cross-linked material.

For claim 47, Botten does not teach the specific width of the adhesive pad.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the adhesive pad be less than 0.2mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105USPQ 233.

For claim, 49, Botten discloses a pad 11 that is substantially uniform in thickness (fig.2).

For claims 51-58, the side of the deformable pad is opposite to the bodyside surface is bonded to a water-permeable, non-woven polyethylene backing layer 13 (col. 3, lines 33-45) that extends radially beyond the adhesive material and is provided with an adhesive layer 14 9col.3, line 52)that extends around the periphery of the backing layer and the backing layer is welded/heat sealed to an ostomy bag (fig. 2 and col. 4, lines 34-35).

For claims 59-63, Botten teaches a pre-formed release liner 12 made of polyethylen terephthalate or a liner that is coated with silicone on both sides, the liner conforms to the shape of the of the bodyside surface of the adhesive material (col. 3, line 63- col. 4, line 12).

For claims 64-65, in addition to the fore-mentioned rejections, Botten and Neumeier teaches a deformable pad 11 consisting of a plastics film 13 bonded to an

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adhesive material, the adhesive layer being covered by a release line 12, the deformable pad having an aperture 5, and the aperture having a convex formation on the bodyside face of the pad and the deformable pad having been formed by moulding a laminate comprising the plastics film, adhesive material, and release liner (col. 5, lines 10-57).

For claims 66-68, Botten teaches that the deformable pad 11 is for removably securing a two-piece ostomy bag having bodyside and bagside elements, the deformable pad being bonded to the bodyside element (fig. 2).

For claims 69-70, Botten teaches a method for producing a deformable pad, the steps are: a) providing a layer of plastics film and a layer of adhesive material, b) shaping the layers of material into a required configuration, and 3) bonding the layers together (col. 5, line 50-col. 6, line 5).

For claims 73-74, Botten teaches that the layers are shaped and bonded with a pre-formed release layer (col. 5, lines 39-40 and line 50- col. 6, line 5).

### ***Allowable Subject Matter***

Claims 50, 71-72 and 75-77 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. patent 5,609,585 and European patent Application 0 756 854 A1 are both drawn to adhesive pads. European Patent Application 0 228 191 A2 is drawn to to an ostomy appliance with a convex formation on the mounting ring.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Linh Truong whose telephone number is 703-605-4974. The examiner can normally be reached on Mondays to Fridays from 8:30am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Calvert can be reached on 703-305-1025. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Linh Truong

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